DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for three approved new animal drug applications (NADA's) from PM Ag Products, Inc., to Sweetlix, LLC.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0214.

SUPPLEMENTARY INFORMATION: PM Ag Products, Inc., 1055 West 175th St., Homewood, IL 60430, has informed FDA that it has transferred ownership of, and all rights and interests in NADA 033–773 for Sweetlix Bloat Guard Block, NADA 109–471 for Staley Sweetlix with Rumensin®, and NADA 136–214 for Enproal Bloat Blox to Sweetlix, LLC, 175 South Main St., suite 150, Salt Lake City, UT 84111. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the transfer of ownership. The agency is removing the sponsor name for PM Ag Products, Inc., because the firm no longer is the holder of any approved NADA's, and the drug labeler code assigned to PM Ag Products, Inc., is being retained as the drug labeler code for Sweetlix, LLC.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

cv00110 NADA 109-471

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List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for "PM Ag Products, Inc." and by alphabetically adding an entry for "Sweetlix, LLC " and in the table in paragraph (c)(2) by revising the entry for "036904 " to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Sweetlix, LLC, 175 South Main St., suite 150, Salt Lake City, UT 84111	036904
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
036904	Sweetlix, LLC, 175 South Main St., suite 150, Salt Lake City, UT 84111
* * *	* * * *

Dated: 2/08/01

February 8, 2001.

cv00110

Claire M. Lathers,
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Center for Veterinary Medicine.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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